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Date


Thomas M. Boyce

Commissioner for Patents
Washington, DC 20231

Re: *U.S. Patent Application No. 10/044,650 entitled "METHODS AND COMPOSITIONS FOR DELIVERY AND RETENTION OF ACTIVE AGENTS TO LYMPH NODES" by Beth A. Goins and William T. Phillips*
Client Reference: 1998-18-US1
Our Reference: UTSK:343US

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references (A1-A12, C1-C90).

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10200210/TMB.

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Respectfully submitted,



Thomas M. Boyce
Reg. No. 43,508

TMB/cmb
Encl.: as noted

25170544.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Beth A. Goins
William T. Phillips

Serial No.: 10/044,650

Filed: January 11, 2002

For: METHODS AND COMPOSITIONS FOR
DELIVERY AND RETENTION OF
ACTIVE AGENTS TO LYMPH NODES

Group Art Unit: 1645

Examiner: Unknown

Atty. Dkt. No.: UTSK:343US

PATENT JUN 25 2002
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Thomas M. Boyce

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10200210/TMB.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Thomas M. Boyce
Reg. No. 43,508
Attorney for Applicants

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List of Patents and Publications for Applicant's
INFORMATION DISCLOSURE STATEMENT
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Atty. Docket No. UTSK:343US	Serial No. 10/044,650
Applicant Beth A. Goins William T. Phillips	
Filing Date: January 11, 2002	Group: 1645

U.S. Patent Documents
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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	4,310,505	1/12/82	Baldeschwieler <i>et al.</i>	424	1	11/8/79
	A2	4,789,736	12/6/88	Canning <i>et al.</i>	534	14	3/11/86
	A3	4,863,713	9/5/89	Goodwin <i>et al.</i>	424	1.1	6/23/86
	A4	4,904,479	2/27/90	Illum	424	490	1/15/87
	A5	5,120,526	6/9/92	Fritzberg <i>et al.</i>	424	1.1	2/4/91
	A6	5,482,698	1/9/96	Griffiths	424	141	4/22/93
	A7	5,690,907	11/25/97	Lanza <i>et al.</i>	424	9.5	6/8/95
	A8	5,698,405	12/16/97	Goldenberg	435	7.5	6/1/95
	A9	5,716,594	2/10/98	Elmaleh <i>et al.</i>	424	1.41	10/2/96
	A10	5,736,119	4/7/98	Goldenberg <i>et al.</i>	424	1.53	3/23/95
	A11	5,776,094	7/7/98	Goldenberg	604	20	6/1/95
	A12	5,792,475	8/11/98	Davis <i>et al.</i>	424	489	7/28/93

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No

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	C1	Alving, "Liposomes as carriers of antigens and adjuvants," <i>J. Immuno Methods</i> , 140:1-13, 1991.
	C2	Barth <i>et al.</i> , "Boron neutron capture therapy of cancer," <i>Cancer Res.</i> , 50:1061-1070, 1990.

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	C3	Bayer and Wilchek, "Avidin- and Streptavidin-containing probes," <i>Methods in Enzymology</i> , 184:174-187, 1990.
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	C5	Chinol <i>et al.</i> , "Biochemical modifications of avidin improve pharmacokinetics and biodistribution, and reduce immunogenicity," <i>Brit. J. Cancer</i> , 78(2):189-197, 1998.
	C6	Coleman, "Chemical sensitizers and protectors," <i>Int. J. Radiation Onc. Biol. Phys.</i> , 42(4):781-783, 1998.
	C7	Corely <i>et al.</i> , "Binding of biotinated-liposomes to streptavidin is influenced by liposome composition," <i>Biochim. Biophys Acta</i> , 1195:149-156, 1994.
	C8	Cox <i>et al.</i> , "Guidelines for sentinel node biopsy and lymphatic mapping of patients with breast cancer," <i>Ann. Surg.</i> , 227(5):645-653, 1998.
	C9	Daemen <i>et al.</i> , "Liposomes and virosomes as immunoadjuvant and antigen-carrier systems in vaccine formulations," In: <i>Medical Applications of Liposomes</i> , Lasic and Papahadjopoulos (eds), Elsevier Science B.V., 117-143, 1998.
	C10	DeCicco <i>et al.</i> , "Lymphoscintigraphy and radioguided biopsy of the sentinel axillary node in breast cancer," <i>J. Nucl. Med.</i> , 39(12):2080-2084, 1998.
	C11	DeFrees <i>et al.</i> , "Sialyl Lewis X liposomes as a mulivalent ligand and inhibitor of E-selectin mediated cellular adhesion," <i>J. Am. Chem. Soc.</i> , 118:6101-6104, 1996.
	C12	DeVita <i>et al.</i> , "Principles of cancer management: cancer genetics," In: <i>Cancer: Principles and Practice of Oncology</i> , 5 th ed., J.B. Lippincott Co., Philadelphia, PA, Chapter 14: 285-293, 1997.
	C13	Gabizon <i>et al.</i> , "Targeting folate receptor with folate linked to extremities of Poly(ethylene glycol)-grafted liposomes: in vitro studies," <i>Bioconjugate Chem.</i> , 10:289-298, 1999.
	C14	Goodman <i>et al.</i> , <i>The Pharmacological Basis of Therapeutics</i> , Gilman <i>et al.</i> (eds), Macmillan Publishing Co., New York, 1985.
	C15	Goodwin <i>et al.</i> , "Pre-targeted immunoscintigraphy of murine tumors with indium-111-labeled bifunctional haptens," <i>J. Nucl. Med.</i> , 29(2):226-234, 1988.

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	C17	Gregoriadis, "Liposomes as immunological adjuvants," <i>The Theory and Practical Application of Adjuvants</i> , 7:145-169, 1995.
	C18	Griffiths <i>et al.</i> , "Direct radiolabeling of monoclonal antibodies with generator-produced Rhenium-188 for radioimmunotherapy: labeling and animal biodistribution studies," <i>Cancer Res.</i> , 51(17):4594-4602, 1991.
	C19	Hader <i>et al.</i> , "Sentinel lymph node biopsy using lymphoscintigraphy," <i>AORN J.</i> , 68:572-588, 1998.
	C20	Heeremans <i>et al.</i> , "Fibrin binding of plasminogen coated liposomes in vitro," <i>Thromb Haemost.</i> , 75(1):134-139, 1996.
	C21	Hermanson, "Preparation of antibody—liposome conjugates," In: <i>Bioconjugate Techniques</i> , Academic Press, San Diego, CA, p.552-553, 1996.
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	C23	Hirnle, "Liposomes for drug targeting in the lymphatic system," <i>Hybridoma</i> , 16(1):127-132, 1997.
	C24	Hnatowich <i>et al.</i> , "Improved tumor localization with (strept)avidin and labeled biotin as a substitute for antibody," <i>Nucl. Med. Biol.</i> , 20:189-195, 1993.
	C25	Hnatowich <i>et al.</i> , "Investigations of avidin and biotin for imaging applications," <i>J. Nucl. Med.</i> , 28(8):1294-1302, 1987.
	C26	Hope <i>et al.</i> , "Production of large unilamellar vesicles by a rapid extrusion procedures. Characterization of size distribution, trapped volume and ability to maintain a membrane potential," <i>Biochim. Et Biophys. Acta</i> , 812:55-65, 1985.
	C27	Jeong <i>et al.</i> , "Avidin-biotin system for targeting metastases: basic aspects," In: <i>Handbook of Targeted Delivery of Imaging Agents</i> , Chapter 18:305-319, CRC Press, 1995.
	C28	Johnsson <i>et al.</i> , "Optimization of drug loading procedures and characterization of liposomal formulations of two novel agents intended for boron neutron capture therapy (BNCT)," <i>J. Liposome Res.</i> , 9(1):53-79, 1999.

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	C29	Kalofonos <i>et al.</i> "Imaging of tumor in patients with indium-111-labeled biotin and streptavidin-conjugated antibodies: preliminary communication," <i>J. Nucl. Med.</i> , 31(11):1791-1796, 1990.
	C30	Kang and Pardridge, "Use of neutral avidin improves pharmacokinetics and brain delivery of biotin bound to an avidin-monoclonal antibody conjugate," <i>J. Pharm. Experimental Therapeutics</i> , 269:344-350, 1994.
	C31	Klibanov <i>et al.</i> , "Blood clearance of radiolabeled antibody: enhancement by lactosamination and treatment with biotin-avidin or anti-mouse IgG antibodies," <i>J. Nucl. Med.</i> , 29(12):1951-1956, 1988.
	C32	Klibanov, "Targeted delivery of gas-filled microspheres, contrast agents for ultrasound imaging," <i>Adv. Drug Delivery Rev.</i> , 37:139-157, 1999.
	C33	Kohno <i>et al.</i> , "Drug delivery systems for infection: liposome-incorporating antimicrobial drugs," <i>J. Infect Chemother.</i> , 4:159-173, 1998.
	C34	Komura <i>et al.</i> , "Thermal neutron capture therapy of malignant melanoma using 10B-monoclonal antibodies: in vitro and in vivo analysis," <i>Melanoma Res.</i> , 1(5-6):397-403, 1991.
	C35	Kotz, "Advancing medical care: the role of nuclear medicine in radioguided surgery," <i>J. Nucl. Med.</i> , 39(12):13N-21N, 1998.
	C36	Krag <i>et al.</i> , "Surgical resection and radiolocalization of the sentinel lymph node in breast cancer using a gamma probe," <i>Surg. Oncol.</i> , 2:335-339, 1993.
	C37	Krag <i>et al.</i> , "The sentinel node in breast cancer—a multicenter validation study," <i>N. Engl. J. Med.</i> , 339(14):941-946, 1998.
	C38	Krause, "Delivery of diagnostic agents in computed tomography," <i>Adv. Drug Delivery Rev.</i> , 37:159-173, 1999.
	C39	Kung <i>et al.</i> , "Antibody-bering liposomes improve agglutination of latex particles used in clinical diagnostic assays," <i>Biochim Biophys. Acta</i> , 839:105-109, 1985.
	C40	Lasic and Pearlman, "Liposomes and lipidic particles in gene therapy," In: <i>Vesicles</i> , Marcel Dekker, New York, 477-489, 1996.
	C41	Leserman <i>et al.</i> , "Ligand targeting of liposomes," In: <i>Liposomes from Biophysics to Therapeutics</i> , Ostro (ed), Marcel Dekker, New York, p. 157-194, 1987.
	C42	Lindblad, "Aluminium adjuvants," <i>Theory Prac. Appl. Adjuvants</i> , 2:21-35, 1995.

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William T. Phillips

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	C44	Magnani <i>et al.</i> , "Quantitative comparison of direct antibody labeling and tumor pretargeting in Uveal melanoma," <i>J. Nucl. Med.</i> , 37(6):967-971, 1996.
	C45	Mayer <i>et al.</i> , "Vesicles of variable sizes produced by a rapid extrusion procedure," <i>Biochim Biophys Acta</i> , 858:161-168, 1986.
	C46	Mayhew <i>et al.</i> , "High-pressure continuous-flow system for drug entrapment in liposomes," <i>Methods Enzym.</i> , 149:64-77, 1987.
	C47	Meares <i>et al.</i> , "Macrocyclic chelates of radiometals for diagnosis and therapy," <i>Br. J. Cancer</i> , 62 (Suppl 10):21-26, 1990.
	C48	Moghimi and Rajabi-Siahboomi, "Advanced colloid-based systems for efficient delivery of drugs and diagnostic agents to the lymphatic tissues," <i>Prog. Biophys. Molec. Biol.</i> , 65:221-249, 1996.
	C49	Moghimi <i>et al.</i> , "Surface engineered nanospheres with enhanced drainage into lymphatics and uptake by macrophages of the regional lymph nodes," <i>FESB Letters</i> , 344:25-30, 1994.
	C50	Morton <i>et al.</i> , "Management of early-stage melanoma by intraoperative lymphatic mapping and selective lymphadenectomy," <i>Surg. Oncol. Clin. N. Am.</i> , 1:247-259, 1992.
	C51	Morton <i>et al.</i> , "Technical details of intraoperative lymphatic mapping for early stage melanoma," <i>Arch. Surg.</i> , 127(4):392-399, 1992.
	C52	New, "Preparation of liposomes," In: <i>Liposomes: A Practical Approach</i> , New (ed), Oxford University Press, NY 33-104, 1990.
	C53	Oehr <i>et al.</i> , "Streptavidin and biotin as potential tumor imaging agents," <i>J. Nucl. Med.</i> , 29:728-729, 1988.
	C54	Ogihara-Umeda <i>et al.</i> , "Rapid diagnostic imaging of cancer using radiolabeled liposomes," <i>Cancer Detection and Prevention</i> , 21(6):490-496, 1997.
	C55	Okuhata, "Delivery of diagnostic agents for magnetic resonance imaging," <i>Advanced Drug Delivery</i> , 37:121-137, 1999.

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U.S. Patent Documents See Page 1		Foreign Patent Documents See Page 1	Other Art See Page 1

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C58	Paganelli <i>et al.</i> , "Monoclonal antibody pretargeting techniques for tumour localization: the avidin-biotin system," <i>Nucl. Med. Commun.</i> , 12(3):211-234, 1991.
	C59	Paganelli <i>et al.</i> , "Potential of the avidin-biotin system for diagnostic application," In: <i>Handbook of Targeted Delivery of Imaging Agents</i> , Chap. 17, CRC Press, 289-303, 1995.
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	C61	Paganelli <i>et al.</i> , "Three-step monoclonal antibody tumor targeting in carcinoembryonic antigen-positive patients," <i>Cancer Res.</i> , 51(21):5960-5966, 1991.
	C62	Paganelli <i>et al.</i> , "Two-step tumour targetting in ovarian cancer patients using biotinylated monoclonal antibodies and radioactive streptavidin," <i>Eur. J. Nucl. Med.</i> , 19(5):322-329, 1992.
	C63	Papisov <i>et al.</i> , "Drug delivery to lymphatic tissue," <i>Crit Rev. Ther. Drug Carrier Syst.</i> , 13(1&2):57-84, 1996.
	C64	Phillips and Goins, "Targeted delivery of imaging agents by liposomes," In: In: <i>Handbook of Targeted Delivery of Imaging Agents</i> , Chap. 10, CRC Press, 149-173, 1995.
	C65	Phillips <i>et al.</i> , "Novel method of greatly enhanced delivery of anti-cancer agents to lymph nodes," <i>9th Annual Symposium on Cancer Research in San Antonio</i> , Abstract #23, July 16, 1999.
	C66	Pykett, "NMR imaging in medicine," <i>Sci Am.</i> , 246(5):78-88, 1982.
	C67	Rao <i>et al.</i> , "A trivalent system from vancomycin-D-Ala-D-Ala with higher affinity than avidin-biotin," <i>Science</i> , 280(5364):708-711, 1999.

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	C69	Reintgen, "The role of lymphoscintigraphy in lymphatic mapping for melanoma and breast cancer," <i>J. Nucl. Med.</i> , 39(12):22N-36N, 1998.
	C70	Runge <i>et al.</i> , "Paramagnetic agents for contrast-enhanced NMR imaging: a review," <i>Am. J. Roentgeno</i> , 141(6):1209-1215, 1983.
	C71	Schechter <i>et al.</i> , "Indirect immunotargeting of CIS-PT to human epidermoid carcinoma KB using the avidin-biotin system," <i>Int. J. Cancer</i> , 48:167-172, 1991.
	C72	Schuber, "Chemistry of ligand-coupling to liposomes," In: <i>Liposomes as Tools in Basic Research and Industry</i> , Philippot and Schuber (eds.), CRC Press, Boca Raton, 21-39, 1995.
	C73	Sigma Catalog, Alphabetical list of compounds, 149-150, 1999.
	C74	Sinitsyn <i>et al.</i> , "Rapid blood clearance of biotinylated IgG after infusion of avidin," <i>J. Nucl. Med.</i> , 30(1):66-69, 1989.
	C75	Sinkula and Yalkowsky, "Rationale for design of biologically reversible drug derivatives: prodrugs," <i>J. Pharm. Sci.</i> , 64:181-210, 1975.
	C76	Stickney <i>et al.</i> , "Bifunctional antibody: a binary radiopharmaceutical delivery system for imaging colorectal carcinoma," <i>Cancer Res.</i> , 51(24):6650-6655, 1991.
	C77	Strand and Bergqvist, "Radiolabeled colloids and macromolecules in the lymphatic system," <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 6(3):211-237, 1989.
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List of Patents and Publications for Applicant's

Applicant
Beth A. Goins
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Other Art
See Page 1U.S. Patent Documents
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